REMARKS/ARGUMENTS

The FINAL Office Action dated June 22, 2006 has been reviewed and the comments have been considered. Claims 1, 6, 7, 10, and 13 have been amended. No new matter has been added by the present amendment. Accordingly, applicants request reconsideration, entry, and allowance of pending claims 1-15.

Claims 1-15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of a "single integrated test device" and the recitation of different combinations of the steps of the claimed method. Applicants respectfully assert that the claims are definite because they recite that the various steps to determine concentration of various markers, drugs, and metabolites are to be used in conjunction with a single device rather than by multiple tests or devices, as stated at page 4, lines 20-30 of the originally-filed application. Thus, one skilled in the art would be apprised of the scope of the claimed method. Further, the combination of various method steps has been deleted by the amendment to claim 1. Accordingly, the rejection under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claims 1-10, 13, and 14 stand rejected under 35 U.S.C. § 102 as being allegedly anticipated by U.S. Patent No. 6,469,035 to Cefali. Claims 1-10, 13, and 14 stand rejected under 35 U.S.C. § 102 as being allegedly anticipated by U.S. Patent No. 5,508,20 to Tiffany et al ("Tiffany"). Applicants respectfully traverse this rejection because Cefali or Tiffany fails to show or describe each and every element of the claimed invention.

As amended, claim 1 recites a method for assessing the effectiveness of a drug therapy and the organ function of a subject using a single integrated test device. The method includes, *inter alia*, the steps of producing, from body fluid samples of the same subject, respective signals indicative of (1) a concentration of an organ marker from a first test strip, (2) concentration of a drug from a second test strip, and (3) concentration of a metabolite from a third test strip. Support for the amendments to claim 1 is provided in the originally filed application at, for example, page 18, lines 8-34 and page 19, lines 1-26.

In contrast, Cefali fails to show or describe producing of a signal indicative of a drug concentration in body fluid samples. Cefali describes, at column 22, lines 18-41, a therapeutic method of treating individuals with a nicotinic acid therapy using a drug identified as NIASPAN®. Cefali describes, at column 23, lines 40-45, the testing of blood

samples to determine various liver enzymes (AST, ALT and Alkaline Phosphate), uric acid and fasting glucose levels. However, Cefali fails to show or describe the determination of any concentration of the drug NIASPAN® that was given to various subjects. Because Cefali fails to show or describe the step of producing signals indicative of concentration of a drug in a body fluid sample with a single test device, Cefali fails to teach or suggest the claimed invention as a whole. Accordingly, claim 1 is patentable over Cefali.

Tiffany, on the other hand, shows and describes, at column 3, lines 34-56, a system to perform reagent analysis at various discrete locations on a single test media. For example, as described at column 15, line 67 to column 16, lines 1-4, five different tests were conducted on an area 17 of paper 11 (Fig. 2). That is, Tiffany shows and describes that various tests may be performed on a single sample on a single test media instead of **three separate test strips** of separate body fluid samples from the same test subject. Because Tiffany fails to show or describe three separate tests on three separate test strip of the same subject in a single test device, Tiffany fails to teach or suggest the claimed invention. Accordingly, claim 1 is patentable over Tiffany.

Claims 11, 12, and 15 stand rejected under 35 U.S.C. § 103 as being unpatentable over Celafi or Tiffany. Applicants respectfully traverse this rejection because Cefali or Tiffany, alone or in combination, fails to teach or suggest the claimed invention as a whole.

The Office Action states that Cefali or Tiffany is silent on the claimed drugs troglitazone, metformin and the metabolite fructosamine. To cure these deficiencies, the Office Action states that it would have been obvious to one of ordinary skill in the art to modify either Cefali or Tiffany to use the claimed features as optimization of result effective variables.

Applicant respectfully submits that the claimed invention as a whole is not an obvious or routine optimization of result effective variables in Cefali or Tiffany for the following reason.

As noted in the Manual of Patent Examining Procedure ("MPEP"), only "results-effective variables" in the prior art can be optimized. *See*, MPEP at 2144.05(II)(B). A result-effective variable is one that achieves a recognized result in the prior art. Such variable must be first identified before the variable can be said to be optimizable. Cefali or Tiffany, as confirmed in the Office Action, fails to identify the drugs troglitazone, metformin or the

metabolite fructosamine at all as result-effective variables to achieve a recognized result. Because Cefali or Tiffany fails to identify the claimed compounds at all or even as result-effective variables to achieve respective recognized results, there were nothing in Cefali or Tiffany that one of ordinary skill could optimize. Consequently, Cefali or Tiffany fails to teach or suggest the claimed invention as a whole, as recited in claims 11, 12, and 15. Accordingly, claims 11, 12, and 15 are patentable over Cefali or Tiffany, alone or in combination, for at least this reason.

Claims 2-15 are also allowable as they depend on allowable claim 1, as well as for reciting additional features.

Applicants respectfully request entry of the amendment as the amendment places the application in condition or in better form for appeal. No new matter would be raised by entry of this amendment because the amendment incorporates the Examiner's suggestions, addresses the Examiner's comments, and entry of the amendment would place the application in condition for allowance. Accordingly, applicants respectfully request entry, consideration and prompt allowance of the application.

Should the Examiner deem a telephonic interview is necessary, he is invited to telephone the undersigned attorney of record at (408) 942-5721. The Commissioner is hereby authorized to deduct any deficiencies, or to credit any overpayment, to Deposit Account No. 10-0750 (DDI0038USDIV/KQT).

Respectfully submitted,

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